

PSJ17 Exh 16

SOP #:	SOP- 8278
TITLE:	Suspicious Order Monitoring – Do Not Ship List

1. PURPOSE

To establish a procedure to maintain a list of suspect potential, current, or former customers, and individuals who may pose an unacceptable risk to TEVA through their purchasing of controlled substances and listed chemicals, or their control of companies who may purchase controlled substances.

2. SCOPE

DEA Compliance personnel will be responsible for maintaining a Do Not Ship List, which will contain a list of potential, current, and former customers who have either been terminated or restricted from purchasing controlled substances and listed chemicals.

3. SUMMARY OF REVISIONS

4. REFERENCES

“Know Your Customer Policy”

“It is fundamental for sound operations that handlers take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, identify those transactions conducted by their customers that are suspicious in nature.”

http://www.deadiversion.usdoj.gov/chem_prog/susp.htm#ela

5. DEFINITIONS

DEA: Abbreviation for the Drug Enforcement Administration

SOM: Abbreviation for Suspicious Order Monitoring

SORDS: The Acronym for TEVA’s SOM Electronic Monitor System

SUSPICIOUS ORDERS: Includes but not limited to orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

DBA: Abbreviation for Doing Business As

SOP #:	SOP- 8278
TITLE:	Suspicious Order Monitoring – Do Not Ship List

PENDED ORDERS: Orders that have been stopped in real time because they breached Teva's SOM algorithm. "Pended" orders are deemed "on hold" until they are investigated. DEA Compliance personnel are the only employees that can review and approve pended orders for DEA Holds.

SUSPICIOUS ORDER OVERSIGHT TEAM: A predetermined team comprised of a representative from DEA Compliance, Customer Service, Legal and Customer Account Management. Certain situations may warrant the addition of other business units at the request and invitation of DEA Compliance.

DNS: Abbreviation for the Do Not Ship List.

6. PROCEDURE

Responsibility Action

6.1 Do Not Ship List

DEA Compliance

6.1.1 The Do Not Ship List will include any customer, potential customer, former customer, or ship to location for which TEVA restricts or terminates their ability to order controlled substances or listed chemicals.

6.1.2 The DNS will include the following information:

- Customer address and all ship to addresses
- Customer DBA (if applicable)
- Name, title and contact information for person responsible for regulatory compliance
- DEA Registration Number(s)
- TEVA National Account Manager
- Name(s) of any relevant principal(s)
- Date of addition to the DNS
- Specific action taken (e.g., restriction of CII sales, cessation of all CS sales)
- Date action lifted (if necessary)
- Reason for action lifted (if necessary)

6.2 Re-Establishing a Closed Account

Suspicious Order Oversight Team

SOP #:	SOP- 8278
TITLE:	Suspicious Order Monitoring – Do Not Ship List

- 6.2.1 A customer on TEVA's Do Not Ship List will not be re-opened unless the customer meets all requirements for a new customer, including an on-site inspection as per SOP-8280. Additionally, the Suspicious Order Oversight Team must approve the account before it is re-opened. Typically, the Suspicious Order Oversight Team will review the full investigation file and will document all changes that occurred after the decision to place the customer on the DNS. If the customer is re-opened, the Suspicious Order Oversight Team will document the reasons for changing the earlier decision. In re-opening the customer, TEVA may require that the customer agree to special terms (e.g., lower monthly purchases for controlled drugs or listed chemicals) and DEA Compliance will periodically monitor or re-investigate to help ensure compliance. Re-opening a closed account should be infrequent.

6.3 Removal of Purchasing Restrictions

Suspicious Order Oversight Team

- 6.3.1 A customer on whom restrictions have been placed via inclusion on TEVA's Do Not Ship List, may have such restrictions reduced or eliminated if the customer provides a mitigation strategy that sufficiently details all of the steps the customer has and will take to prevent the diversion of controlled substances.
- 6.3.2 The Suspicious Order Oversight Team will analyze the customer's mitigation strategy. The mitigation strategy, along with the Suspicious Order Oversight Team's analysis and decision(s), will be documented and maintained in the customer's DEA Compliance File. Resolution will also be noted on the DNS along with the date of the resolution.

6.4 Customer Site Visits

DEA Compliance

- 6.4.1 Customer site visits will be performed according to SOP-8280.

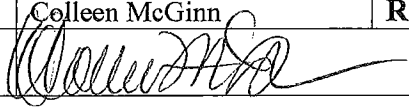
6.5 Confidentiality

- 6.5.1 The DNS is a confidential document, and will not be shared outside of TEVA, nor will any of its contents be shared outside of TEVA.

7. ATTACHMENTS

N/A

SOP #:	SOP- 8278
TITLE:	Suspicious Order Monitoring – Do Not Ship List

Written/Revised By:	Joseph Tomkiewicz	Effective Date:	8/1/14
Approved By:	Colleen McGinn	Revised Date:	N/A
Approver Signature:			

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QUIZ

1. The Do Not Ship List may contain:
 - A. Former Customers
 - B. Potential Customers
 - C. Active Customers
 - D. Individuals
 - E. All of the Above

2. A customer who has been terminated may be reinstated by the Suspicious Order Oversight Team.

TRUE or FALSE

3. The Do Not Ship List may be shared with other manufacturers or wholesalers.

TRUE or FALSE

SIGNATURES

Employee (print name):	
Employee (signature):	Date:

<i>Quiz answers checked for correctness. All questions incorrectly answered were discussed with the employee and understood.</i>	
Instructor (signature):	Date:

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